

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TENNESSEE  
SOUTHERN DIVISION AT CHATTANOOGA**

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ANGELA MONTGOMERY,	:	
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Plaintiff,	:	
	:	No. 1:05-CV-00323
v.	:	
WYETH, f/k/a American Home	:	
Products Corp., et al.,	:	
	:	
Defendants.	:	

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**WYETH'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF ITS  
MOTION FOR SUMMARY JUDGMENT PURSUANT TO T.C.A. § 29-28-103**

**I. The Diet Drug Class Action Settlement Has No Bearing On The Bar of The Statute of Repose.**

Plaintiff makes several arguments based on the Diet Drug National Class Action Settlement Agreement. (Ex. 13 to Plaintiff's Opposition.) Every one of those arguments is premised on factual assertions and "interpretations" of the Agreement that are indisputably wrong.

First, plaintiff repeatedly argues that "more than five (5) years prior to the filing of her Complaint [she] asserted her claims as a member of the class action . . ." (Pl's Opp. at p.11; see also pp. 13-17.) In making that argument plaintiff does not even bother to attach to her brief the class action complaint in which her PPH claim was supposedly first asserted. A copy of that complaint (and the three amendments thereto) are, however, attached hereto as Exhibits "A," "B," "C," and "D." These complaints make it crystal clear that plaintiff's PPH claim was never asserted in the class action proceedings in any way. The only claim asserted in the Class Complaint is for damage to heart valves and it is clear and explicit in excluding any claims for PPH. The introductory paragraph makes this clear:

The proposed class and subclasses do not include any claims based upon a diagnosis by a qualified physician of primary pulmonary hypertension (“PPH”) suffered by a diet drug recipient.

Class Complaint ¶ 1, pp. 1 – 2. This point is reiterated in the paragraph that defines the class:

The proposed class and subclasses do not include any claims based upon a diagnosis by a qualified physician of primary pulmonary hypertension (“PPH”) suffered by a diet drug recipient.

Class Complaint ¶ 13, p. 5. So, the entire premise of plaintiff’s argument regarding the Class Action is contrary to undisputed fact.

Plaintiff also grossly misstates the record in her repeated assertions that her case – as part of the class complaint – “has never been dismissed, but has been and still is pending” Pl’s Opp. at p. 15; see also pp. 16 – 17. The truth, however, is that the Class Complaint was dismissed by Judge Bechtle at the same time he approved the Settlement Agreement, in August 2000:

The Court hereby dismisses, with prejudice...the  
Third Amended Complaint in this action...

In re Diet Drugs Prod. Liab. Litig., Pretrial Order No. 1415, MDL No. 1203, 2000 U.S. Dist. Lexis 12275, at 53 (E.D. Pa. Aug. 28, 2000) (Exhibit “1” to Pl’s Opp.). Thus, even if Plaintiff were correct that her PPH claim had somehow been asserted as part of the class complaint, that complaint was dismissed more than five years before this suit was filed.

Plaintiff’s purported reliance on Cronin v. Howe, 906 S.W. 2d 910 (Tenn. 1995), is thus entirely lacking in merit. Unlike in Cronin, plaintiff here did not file an initial action asserting her claim within the statute of repose. Moreover, unlike Cronin, the current suit was not re-filed within a one-year period following the dismissal of an initial action allowed by any “savings statute.” Even if a savings statute were theoretically applicable here – and it is not – it could not be invoked where there has been a gap of more than five years between the dismissal of the initial filing and the current complaint. Cronin simply reinforces Wyeth’s motion in that it

makes clear that even if an initial filing is filed within the statute of repose and then dismissed, such filing cannot save a later filing from the bar of the statute of repose unless (i) a savings statute is applicable and (ii) the second action has been filed within the period provided therein. Here, that is clearly not the case.

Plaintiff's apparent attempt to somehow rely on language in the Settlement Agreement dealing with statutes of limitation on PPH claims also misses the mark. The Settlement Agreement, because it did not encompass claims of PPH, preserves the rights of diet drug users to bring such claims, unimpeded by the Settlement Agreement or the injunction against the prosecution of settled claims. It is in that sense, that the right to file a lawsuit for PPH damages is indeed "fully preserved."

To ensure that class members not seek recovery for settled claims by the subterfuge of applying the label "PPH" to conditions which are not PPH, the Settlement Agreement contains a specific definition of PPH and bars the filing of so-called PPH claims unless that definition is satisfied. See PTO 2383, attached as Exhibit "14" to Pl's Opp. The Settlement Agreement further specifies:

For purposes of any statute of limitations or similar time bar [Wyeth] shall not assert that a Class Member actually had PPH unless and until the condition of the Class Member meets the definition of PPH set forth in Section I. 46.

There are at least two independent reasons why this provision has no relevance to the bar of the statute of repose. First, the Tennessee statute of repose is not a statute of limitations, nor is it a "similar time bar." Rather, Tennessee has explicitly recognized that statutes of limitations and statutes of repose serve fundamentally different purposes. When the parties to the Settlement Agreement intended to immunize class members from a statute of repose they knew how to do so and did so explicitly. With respect to class members who exercised certain limited

“intermediate” or “back-end” opt-out rights regarding claims of valvular heart disease, during the narrow time period specifically allowed for such claims, the Settlement Agreement specifies that:

[Wyeth] shall not assert any defense based on any statute of limitations or repose or the doctrine of laches... [or] any other defense predicated on the failure to timely pursue the claim.”

Settlement Agreement § IV. D. 3 (p. 56); IV. D. 4 (p. 60). Thus the absence of any limits on Wyeth asserting the “statute of repose” with respect to PPH claims can only be construed to reflect the parties’ intent.

Second, even if the reference to a “similar time bar” could be construed to encompass Tennessee’s statute of repose, it would still be inapposite. The Settlement Agreement does not say – as it does for intermediate and back-end opt-outs – that Wyeth “shall not assert” the statute of limitations or any other time bar with respect to PPH claims. Indeed, Judge Bartle has specifically recognized Wyeth’s right to assert the statute of limitations in a PPH case. See Mingus v. Wyeth, MDL Docket No. 1203, Civil Action No. 04-23744, 2006 WL 1050289, \*3 (E.D. Pa. Apr. 20, 2006) (concluding “at the very least, a plaintiff must act with reasonable diligence under the circumstances to obtain all the examinations and tests in order to determine whether she meets the definition of PPH as written into § I.46”). Rather, the only restriction on Wyeth’s ability to assert the statute of limitations or any “similar time bar” as to PPH claims is that Wyeth is precluded from contending that a plaintiff “actually had PPH” prior to meeting the Settlement Agreement definition. Here, Wyeth is plainly not contravening the above restriction. Wyeth’s motion is not premised on any claim that plaintiff “actually has PPH.”<sup>1</sup> Rather,

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<sup>1</sup> Indeed, Wyeth’s experts have opined that she does not have PPH.

Wyeth's motion is based on the expiration date of the product, a consideration which is entirely separate from whether plaintiff has PPH or any other injury.

Finally, Plaintiff complains that the statute of repose taken together with the Settlement Agreement creates an unfair "Catch-22". (Pl's Opp. at 13.) Again, that argument ignores both the law and the facts. It is well-established that Tennessee's statute of repose can indeed bar an action before it ever accrues. See Spence v. Miles, 37 F.3d 1184 (6th Cir. 1994). Thus, even if that were the case here, it would provide no basis for disregarding the statute of repose. But, as pointed out in Wyeth's opening brief (Sec. I), the facts of this case do not even present the sort of scenario present in Spence. Plaintiff's own experts and treating doctors have opined that Plaintiff had her first symptoms of PPH in 2000 and had been suffering from the disease, i.e., that she actually had PPH, months and months prior to that. If they are correct, then Plaintiff could certainly have met the Settlement Agreement's PPH definition and filed this action well before the September 2001 statute of repose deadline and there is no inequity or Catch-22 element in the enforcement of the statutory bar.

In sum, Plaintiff's purported reliance on the Class Action Settlement Agreement is a smokescreen. Nothing in the filing of the Class Complaint or the execution or the approval of the Settlement Agreement has any bearing whatsoever on the proper application of the statute of repose in this case.

## **II. Wyeth Timely Asserted And Never Waived The Statute of Repose Defense.**

In its Answer, Wyeth stated that "Plaintiff's causes of action are barred in whole or in part by the applicable statutes of limitations and repose," and specifically pled all "defenses of the Tennessee Products Liability Act of 1978, codified in Tennessee code Annotated §§ 29-28-101 through 108." (Answer, pp. 2 & 32). The Statute of Repose, codified at subsection 29-28-

103 of the Act, is plainly one of the defenses Wyeth has asserted. Plaintiff's arguments of waiver strain credulity.

When Plaintiff originally raised waiver in opposing Wyeth's Motion to Amend Scheduling Order, she cited Tennessee state court Rule of Civil Procedure 8.03 as requiring greater specificity in asserting a defense of "statute of repose," even though it does not apply here. In her Opposition here, she basically repeats the argument, but without any legal support. Federal Rules of Civil Procedure 8 and 9 impose no requirement for heightened pleading of a statute of repose defense. Rather, Fed. R. Civ. P. 8(e) requires that averments in pleadings be "simple, concise, and direct," and specifies that "[n]o technical forms of pleading . . . are required." It also makes clear that a "party may also state as many separate claims or defenses as the party has regardless of consistency." Wyeth's Answer clearly follows the Rules and asserts a statute of repose defense in two places. It is not surprising that plaintiff has not cited a single case finding waiver under such circumstances.

Even if Wyeth did have some obligation to not "ke[ep] plaintiff's Counsel in the dark" about the "three basic facts" entitling Wyeth to summary judgment under § 29-28-103(a), as plaintiff argues in her Opposition, she ignores that these "basic facts" are all in her Complaint. Plaintiff asserted that she was a resident of Tennessee, that she took Pondimin "during 1996 and the first part of 1997," and that Pondimin was "withdrawn from the market on September 15, 1997." (Complaint at ¶¶ 1, 4, 36.) The Complaint itself leaves no doubt that it was not filed until October 2005. So, plaintiff was aware of the facts underlying Wyeth's statute of repose defense when she filed her Complaint.<sup>2</sup> Having pled a statute of repose defense, Wyeth was

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<sup>2</sup> When her case was transferred to the MDL, plaintiff gained access to documents in the Pondimin New Drug Application, including those dealing with the product's expiration date. Continued on following page

under no obligation to file a motion before it did — in fact, Wyeth filed its motion three weeks before the deadline.<sup>3</sup>

This Court in Spence v. Miles Labs., Inc., 810 F. Supp. 952, 965-66 (E.D. Tenn. 1992), rejected a far stronger waiver argument in granting summary judgment based on § 29-28-103(a). In Spence, the answer stated a general defense that the complaint was barred by the applicable statute of limitations and statute of repose without citing a specific statute. Five weeks before trial, the defendant specified that the medical malpractice statute of repose, § 29-26-116(a)(3), barred the claims. Three weeks later — just two weeks before trial — the defendant raised § 29-28-103(a) for the first time. Because the defendant “did generally assert the defense that the complaint is time-barred by the applicable statute of repose in its answer,” the court found no waiver and granted summary judgment. Id. at 966. Here, Wyeth’s answer not only asserted the applicable statute of repose, but referenced the defenses in the Tennessee Product Liability Act, of which the statute of repose is a well-known defense. Moreover, Wyeth never advocated that a different statute of repose applied and moved under § 29-28-103(a) in advance of the summary judgment deadline almost five months before trial. Even more so than in Spence, to find waiver here would be “manifestly unjust.”<sup>4</sup> See id.

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Her counsel, whose Declaration describes his own extensive involvement with litigation involving Pondimin long before getting involved in this case, had these documents years earlier.

3 After Wyeth removed this case, it was transferred to the MDL court, which Wyeth knew had not entertained case-specific motions for summary judgment in the past. See, e.g., MDL PTO 2830 (denying a motion for summary judgment on statute of limitations without prejudice because the issue “is not one of general applicability to the MDL cases presently before this Court” and stating that the motion could be renewed after remand to the transferor court). A motion for summary judgment in this Court after remand from the MDL was the proper vehicle for asserting the statute of repose defense. At the September 7, 2007, status conference, Wyeth was under no obligation to specify—on pain of waiver—the grounds for summary judgment that it would assert in accordance with the Court’s pretrial schedule.

4 The predominant view is that the statute of repose is not waivable. In Bruce v. Hamilton, 894 S.W.2d 274, 275 (Tenn. App. 1993), the Court of Appeals recognized that the statute of repose  
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### **III. There Is No Genuine Dispute of Material Fact about The Operation of § 29-28-103 Here**

Plaintiff has made several arguments in an attempt to create the illusion of a factual dispute, but none of her arguments begin to create a “genuine dispute as to a material fact” concerning the timing of the running of the statute of repose. Under § 29-28-103, two facts are material to the running of the statute of repose based on the “expiration of the anticipated life” of the Pondimin tablets that plaintiff took: 1) that the Pondimin tablets taken by plaintiff left Wyeth’s control in packaging bearing an expiration date pursuant to a legal requirement, and 2) that the expiration dates for the Pondimin tablets that plaintiff took were all more than one year before she filed suit. Wyeth established both of these facts through the Declaration of Harry Joslin attached to its motion. That Declaration explained that *all* Pondimin tablets sold by Wyeth in the United States were packaged in packaging bearing an expiration date pursuant to Wyeth’s practice and applicable law and that the expiration date on all packaging was no later than September 2000. Mr. Joslin’s Declaration has not been contradicted in any respect.

Rather, Plaintiff contends that (1) “the bottles in which the pills were given to me” — by Med-X Clinic — did not have “an expiration date on them,” (2) that she was unaware of the expiration dates for the Pondimin tablets she took, and (3) that it is not clear what the precise expiration date was for each of the Pondimin tablets she took. The first of these contentions is legally and factually irrelevant. The “expiration of the anticipated life of the product” for

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was a substantive issue relating to the Court’s subject matter jurisdiction and, therefore, cannot be waived. Despite plaintiff’s claim that Cronin v. Howe, 906 S.W.2d 910 (Tenn. 1995), overruled Bruce in all respects, it actually agreed that the statute of repose was substantive. Cronin, 906 S.W.2d at 914. Similarly, the Sixth Circuit has held that a statute of repose cannot be waived by failing to raise it as an affirmative defense. Roskam Baking Co., Inc. v. Lanham Machinery Co., Inc., 288 F.3d 895, 902 (6th Cir. 2002); Hayes v. General Motors Corp., No. 95-5713, 1996 WL 452916, at \*4 (6th Cir. Aug. 8, 1996). Because the facts here do not support waiver at all, the Court need not determine whether there could be waiver under other facts.

purposes of the statute of repose depends on the expiration date on the packaging of the product *as sold* by the manufacturer, not whether the plaintiff gets the product in its original packaging. As § 29-28-102(1) states, “[t]he anticipated life of a product shall be determined by the expiration date *placed on the product by the manufacturer when required by law.*” See also Spence v. Miles Labs., Inc., 37 F.3d 1185, 1190 (6th Cir. 1994) (discussing packaging of product by manufacturer). Consistent with the legal requirements of 21 CFR 201.17 & 211.137, the expiration date for Pondimin tablets appeared on the packaging for the 100 and 500 count trade bottles that Wyeth sold to distributors and authorized dispensers. Joslin Decl., ¶ 4, Ex. C to Wyeth’s Mo. Wyeth did not sell Pondimin tablets to plaintiff (or any consumer). Joslin Supp. Decl., ¶ 7, attached hereto as Ex. E. Plaintiff bought her Pondimin tablets from Med-X, which re-packaged the tablets into a bottle containing 90 tablets. Pl’s Decl., ¶ 3, Ex. 11 to Pl’s Opp.; Joslin Supp. Decl., ¶ 7, Ex. E. Thus, she did not get Wyeth’s packaging. Therefore, even crediting her Declaration,<sup>5</sup> her claim that the bottles she got from Med-X did not have an expiration date casts no doubt on, and is unrelated to, the undisputed fact that Wyeth’s packaging for its Pondimin tablets bore a legally mandated expiration date. The purpose of the statute of repose would be frustrated if its operation depended not on “the expiration date placed on the

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<sup>5</sup> Although plaintiff’s January 2008 Declaration purports to provide details about what she did and did not see or know in 1997, her deposition testimony from 2006 presents a far different picture of her recollection of her prescriptions for Pondimin. She did not know the names of the physicians who prescribed her diet drugs, was not sure what she talked about with these physicians, did not remember receiving oral instructions about side effects of the medications, and did not remember if she received any written information about the medications. Montgomery Dep., 7/27/06 at 111 & 187-90, attached hereto as Ex. F. Nor did she remember the size or color of the medications she was prescribed or how many she was supposed to take daily. Montgomery Dep., 8/30/06 at 62-63, attached hereto as Ex. G. In light of this lack of personal knowledge, the claims in plaintiff’s much later Declaration that she remembers that the Med-X bottles containing the “Fenphen” she received did not have expiration dates and that she was never told “not to take them after a certain date or return them after a certain date” are not sufficiently reliable to create any issue of fact. Pl’s Decl. at ¶¶ 7 & 9, Ex. 11 to Pl’s Opp.

product by the manufacturer when required by law," but on whether a downstream purchaser plaintiff received original packaging.

The second of Plaintiff's contentions is also unavailing. Her recollection of her knowledge of the expiration date for the Pondimin she took is simply not relevant to the statute of repose. In Spence, the statute of repose barred the suit even where there was no indication that the decedent had been aware of the expiration date for the blood products he was administered. See 37 F.3d at 1190; Spence v. Miles Labs., Inc., 810 F. Supp. 952, 957, 959-60 (E.D. Tenn. 1992). No reported case has superimposed any knowledge requirement upon the statute itself, which does not turn on what a potential plaintiff knew or should have known. Indeed, if anything, the statute of repose is premised on the knowledge of the expiration date *by the manufacturer*, which uses that information in setting insurance reserves.

The last of Plaintiff's contentions also fails to create a genuine issue of material fact. Although it is correct that there is no information in the record as to the precise expiration date for the lots of Pondimin tablets that plaintiff took, there is no genuine dispute of *material* fact because it is undisputed that the expiration dates were all at least five years before plaintiff brought suit. Nor does plaintiff's injection of foreign-source "fenfluramine" used to make Pondimin tablets matter here.<sup>6</sup> Wyeth did not purchase Pondimin tablets from any foreign source. Joslin Supp. Decl. at ¶ 15, Ex. E. The only thing acquired from Servier in France was bulk fenfluramine which was used in making Pondimin tablets at Wyeth's facility in Richmond. Id. As the Supplemental Declaration makes clear—if there was any doubt from his original declaration—any Pondimin tablets that plaintiff took all had expiration dates before October

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<sup>6</sup> If plaintiff did not take Pondimin tablets manufactured by Wyeth but only a Fenfluramine-containing product manufactured by someone else, then there might be some question as to the applicable expiration dates—but there would also be no viable claim against Wyeth at all.

2000. “Pondimin 20 mg tablets purchased from Wyeth in the United States or from a distributor who obtained Pondimin from Wyeth in the United States were all manufactured and packaged in Richmond and in packaging bearing the expiration date for each lot.” Id. at ¶ 5, Ex. E. “No lot of Pondimin 20 mg tablets manufactured or packaged by Wyeth had an expiration date of October 2000 or later.” Id. at ¶ 6. Since Plaintiff claims to have been injured by the Pondimin 20 mg tablets she took in 1997, which had an anticipated life expiring before October 2000, the statute of repose required plaintiff to bring her suit against Wyeth before October 2001. Plaintiff did not bring her suit until October 2005. There is simply no genuine issue of material fact here.

#### **IV. TENNESSEE LAW APPLIES TO PLAINTIFF’S CLAIMS**

##### **A. Plaintiff Has Always Claimed That Tennessee Law Applies**

Plaintiff’s novel claim that Georgia law applies flies in the face of Plaintiff’s consistent representations to this Court that substantive Tennessee law applies to this case:

- **Plaintiff claimed that punitive damages must be determined under Tennessee law.** See Deposition of Everett Dillman, 11/2/07, at 25 – 26, Ex. H (plaintiff’s counsel clarifying that Dr. Dillman’s punitive damages assessment is based on the requirements of Tennessee law); Plaintiff’s Identification of Economic Experts and Proffer of Expert Reports, stating Dillman’s Report “was amended to reference Tennessee law, including the case of Memphis Light, Gas & Water Division v. Tommy Carl Starkey, 2007 Ten. App. LEXIS 439”; Pl’s Opp. to Wyeth’s Mot. Exclude or Limit Testimony of Everett Dillman, Ph.D., at 4-6 (arguing the substantive law on punitive damages in this case is a matter of Tennessee state law);
- **Plaintiff claimed that damages must be determined under Tennessee law.** See Pl’s Opp. Mot. Exclude or Limit Testimony of Lori Hinton, Ph.D., at 8 & 11 - 12 (outlining damages law under heading entitled “Damages Law in Tennessee”)
- **Plaintiff claimed that causation must be determined under Tennessee law.** See Plaintiff’s Omnibus Daubert Motion, p. 28 (citing Denton v. Southern Ry. Co., 854 S.W.2d 885, 886 (Tenn. 1993)).

- Plaintiff claimed that Tennessee law governs Plaintiff's design defect and inadequate warnings claims. See Memorandum in Support of Plaintiff's Motion To Admit Evidence of All Risks and Benefits of Pondimin and Redux. Plaintiff's entire brief was based on substantive Tennessee law. See 1-2 (outlining "basic points of Tennessee law" on whether a product is "unreasonably dangerous"); 3 (arguing what risk evidence plaintiff believes is admissible under Tennessee law); 4-5 (outlining plaintiff's recitation of prescription drug manufacturer liability under Tennessee law); 7 (explaining that resolution of her defective design and inadequate warnings claims require application of Tennessee law). Plaintiff could hardly have been more clear about what law applied, stating "***Resolution of this issue requires application of the substantive law of Tennessee.***" *Id.* at 7.
- Plaintiff's oppositions to Wyeth's **Daubert Motions** claimed that Tennessee law applied. See Plaintiff's Opp. to Mot. Exclude or Limit the Testimony of Cheryl Blume, Ph.D., at 7 n.3 (arguing that adverse event report evidence is admissible under Tennessee law); 12 (complaining that Wyeth's motion contains no Tennessee law that says only a medical doctor may opine on the risk and benefits of a drug); Pl's Opp. to Wyeth's Mot. Exclude or Limit Testimony of Keith Altman, at 3 (arguing that adverse event report evidence is admissible under Tennessee law).
- Plaintiff has never before argued that Wyeth incorrectly relies on Tennessee law in its motions or in any other facet of this litigation. See, e.g., Wyeth's Mot. Exclude or Limit the Testimony of Jack Wilmore, Ph.D., at 9-10 (reviewing and applying Tennessee state law on whether a product is unreasonably dangerous), Wyeth's Mot. Exclude or Limit the Testimony of Everett Dillman, Ph.D., at 10 (citing Tennessee law for requirement that life care plans must be based on reasonably certain evidence for admissibility); 12-13 (citing Tennessee law for factors to consider when assessing punitive damages), Wyeth's Mot. Exclude or Limit Testimony of Lori Hinton, Ph.D., at 5 (reviewing Tennessee law on recovery of future damages).

Prior to being confronted with Wyeth's Motion on the Tennessee statute of repose, Plaintiff never so much as cited a single Georgia case before this Court, much less claimed that Georgia law applied, which belies Mrs. Montgomery's self-serving claim that she "understood" that Georgia law would apply. (Ex. 11 to Plaintiff's Br., Pls. Declaration, at ¶ 10). Plaintiff even

objected to postponing Daubert hearings in light of Wyeth's statute of repose motion even though the Daubert briefs and Plaintiff's supporting motion *in limine* relied on Tennessee law, not Georgia law.

**B. Contrary to Plaintiff's Claim, Georgia Law Conflicts With Tennessee Law In Areas Other Than the Statute of Repose**

Plaintiff claims that she did not raise Georgia law sooner because Wyeth had not raised the Tennessee statute of repose, and as a result, there was no actual conflict. In reality, Plaintiff was fine with Tennessee law until Wyeth moved for summary judgment on the part of Tennessee law that requires dismissal of Plaintiff's claims. Plaintiff therefore feigns surprise at Wyeth's statute of repose motion, but Wyeth had raised the Tennessee statute of repose in its Answer *on November 28, 2005*, which explicitly stated that "Plaintiff's causes of action are barred in whole or in part by the applicable statutes of limitations and repose," separately pleaded reliance on "defenses of the Tennessee product Liability Act of 1978, codified in Tennessee code Annotated §§29-28-101 through 108," which includes the statute of repose therein, and raised a *dozen* other Affirmative Defenses that explicitly relied on Tennessee law.<sup>7</sup> See Answer. If Plaintiff believed that the Tennessee defenses raised in Wyeth's Answer were not available because Georgia law applied, then Plaintiff should have been claiming that Georgia law applied from the moment Wyeth filed its Answer two-and-a half years ago.<sup>8</sup>

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<sup>7</sup> The Twelfth, Thirteenth, Thirtieth, Thirty-First, Thirty-Ninth, Forty-Fifth, Forty-Sixth, Forty-Seventh, Forty-Eighth, Forty-Ninth, Fiftieth, Fifty-First, and Fifty-Second Affirmative Defenses *all explicitly rely on Tennessee law*. See Answer.

<sup>8</sup> Plaintiff's lawyer's gratuitous reference to the supposed value of the billable hours spent by his firm on this litigation ignores the fact that, until last week, *all of it has been accumulated by Plaintiff's counsel arguing that Tennessee law applies to this case*. The fact that Plaintiff's lawyers have a contingency fee arrangement does not permit them to erase the law they claim is applicable once they realize that they will not make a recovery. This inappropriate reference to the lawyers' pocketbooks has no place before this Court.

Plaintiff's claim that Georgia law does not conflict with Tennessee law aside from the statute of repose is wrong. The Complaint, for example, purports to bring a claim under Restatement of Torts (Second) 402(B), which has been recognized in other contexts in Tennessee.<sup>9</sup> See, e.g., Messer Griesheim Indus., Inc. v. Cryotech of Kingsport, Inc., 131 S.W.3d 457, 468 (Tenn. Ct. App. 2003). No Georgia court has recognized such a claim in any circumstance. Moreover, Wyeth's Answer pleaded a defense under T.C.A. § 29-28-104, which provides:

Compliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions for use of a product, shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards.

Georgia law has no similar presumption. See Banks v. ICI Americas, Inc., 264 Ga. 732, 736, n.6 (Ga. 1994) (“We note that a manufacturer's proof of compliance with industry-wide practices, state of the art, or federal regulations does not eliminate conclusively its liability for its design of allegedly defective products.”). Nevertheless, just last month Plaintiff unequivocally insisted that Tennessee law applied to Plaintiff's claim that Pondimin was unreasonably dangerous because it should not have been marketed. In that regard, Georgia does not recognize Tennessee's statutory “prudent manufacturer” test under T.C.A. § 29-28-102 (8), instead relying on a more general risk/benefit analysis outside of the context of whether the manufacturer would have placed the product on the market. Compare Ray ex rel. Holman v. BIC Corp., 925 S.W.2d 527, 532 (Tenn. 1996) (“the prudent manufacturer test imposes liability in circumstances in which a reasonably prudent manufacturer with knowledge of a product's dangerousness would

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<sup>9</sup> Wyeth disputes the availability of a 402(B) claim under applicable Tennessee law, but the Plaintiff apparently believes that such a claim exists having pleaded it in the Complaint.

not place the product in the stream of commerce.”), with Banks, 264 Ga. at 736 (“it is only at their most extreme that design defect cases reflect the position that a product is simply so dangerous that it should not have been made available at all”).

Further, as the Opposition indicates, there are substantial differences in how Tennessee and Georgia award punitive damages. While Plaintiff trumpets Georgia’s supposed interest in having its punitive damages law apply, Plaintiff ignores Barger v. Garden Way, Inc., 231 Ga.App. 723, 728 (Ga. App. 1998), which held that compliance with industry regulations precludes an award of punitive damages. See also Stone Man, Inc. v. Green, 263 Ga. 470, 472 (Ga. 1993) (“such compliance does tend to show that there is no clear and convincing evidence of ‘willful misconduct, malice, fraud, oppression, or that entire want of care which would raise the presumption of [a] conscious indifference to [the] consequences’”).

Each of these issues was apparent the moment the Plaintiff filed the Complaint. Plaintiff’s sudden about-face on Tennessee law is a disingenuous attempt to avoid the statute of repose, would render many of their briefs, depositions, and expert reports irrelevant, and begs the Court to ignore countless representations made by the Plaintiff that Tennessee law applies.<sup>10</sup> Georgia law does not apply to this case under Tennessee’s choice-of-law rules, and it is no surprise that Plaintiff has not previously urged the application of Georgia law.

### **C. Tennessee Has The Most Significant Contacts To This Case**

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<sup>10</sup> Plaintiff should not be permitted to “play[] fast and loose with the courts,” or “blow[] hot and cold as the occasion demands.” Reynolds v. C.I.R., 861 F.2d 469, 472 (6th Cir. 1988) (internal quotations omitted); see New Hampshire v. Maine, 532 U.S. 742, 750-51 (2001) (forbids “intentional self-contradiction … as a means of obtaining unfair advantage”). Plaintiff’s purported reliance on Warner v. Fuller Rehab. & Consulting Services, 2005 U.S. Dist. LEXIS 41699, \*7, n.3 (E.D. Tenn. 2005) is entirely misplaced. There, the Court was not applying Tennessee’s choice-of-law principles, but was enforcing the parties contractual choice-of-law election. Here, by the course of conduct throughout two-and-a half years of litigation, the parties have demonstrated their mutual election to be governed by Tennessee law.

In a diversity case, the Court must apply the law of the forum state, including the forum's choice of law rules. See, e.g., Erie R.R. Co. v. Tompkins, 304 U.S. 64, 78 (1938); Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496-97 (1941). Tennessee has adopted the Restatement's "most significant relationship" approach to determining choice-of-law questions.<sup>11</sup> See Hataway v. McKinley, 830 S.W.2d 53, 57 (Tenn. 1992). As Hataway noted, "[u]nder this approach, a court applies the 'law of the state where the injury occurred ... unless, with respect to the particular issue, some other state has a more significant relationship ... to the occurrence and the parties.'" Id. citing Restatement (Second), §§ 146 and 175). The court recognized that "generally the law of the state where the injury occurred will have the most significant relationship to the litigation." Id. at 59. In rejecting other choice-of-law tests, the court further noted that "the Restatement is easier to apply in difficult cases because it provides a "default" rule whereby trial courts can apply the law of the place where the injury occurred when each state has an almost equal relationship to the litigation. Id. (emphasis added). See also Bostick v. St. Jude Medical, Inc., No. 03-2626 BV, 2004 WL 3313614, \*12 (W.D. Tenn. 2004) ("there is a presumption in Tennessee that the law of the location of the injury controls").

Cases holding that the place of injury did not control the choice-of-law decision have done so only when the place of injury had been found to be truly "fortuitous." See, e.g., Bramblett v AVCO Corp., No. 03A01-9309-CV-00302, 1994 WL 110185, \* 3 (Tenn. App. Apr. 5, 1994) (place of injury was "fortuitous" when plane carrying Tennessee residents to and from Tennessee happened to crash in Kentucky); Hataway, 830 S.W.2d at 57 (place of injury was "fortuitous" when Tennessee resident taking a course at Memphis State died while diving in

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<sup>11</sup> There is no dispute that Tennessee and Georgia law conflict with respect to the statute of repose. Georgia does not have a statute of repose relating to "the expiration of the anticipated life of the product."

Arkansas); Lemons v. Cloer, 206 S.W.3d 60, 67 (Tenn. Ct. App. 2006) (place of injury was “fortuitous” when Georgia schoolbus taking Georgia residents to and from school in Georgia happened to pass briefly thru Tennessee, where accident occurred). Certainly here the place of Plaintiff’s injury cannot be deemed fortuitous: she is a lifelong resident of Tennessee and claims that she developed a disease in Tennessee because she took drugs which she purchased with the intent of consuming them in Tennessee and which she then did consume in Tennessee. Plaintiff cites no case, and we are aware of none, where Tennessee has applied another state’s law to the claims of a Tennessee resident who suffered an injury in Tennessee resulting from conduct purposefully conducted by the Plaintiff in Tennessee.

The Court has no reason to deviate from the default rule in this case, where plaintiff’s injury clearly occurred in Tennessee and the contacts with Tennessee are ***overwhelming and undisputed***:

- Plaintiff is a life-long resident of Chattanooga, Tennessee. See Complaint at ¶ 1; Montgomery Dep., 7/27/06, at 17:20-18:4, Ex. F.
- Her purpose in going to Georgia was to obtain drugs so that she could bring them back to Tennessee for her personal use in Tennessee. Montgomery Dep., 8/30/06, at 68-69, Ex. G; Ex. 11 to Plaintiff’s Br., Pls. Decl., at ¶ 6.
- Plaintiff ingested Pondimin in Tennessee almost every single day for seven months. Montgomery Dep., 8/30/06, at 63 (claiming that she took all of the pills), Ex. G
- Plaintiff claims that she experienced her first symptoms on May 21, 2000, when she passed out at a football game in Tennessee, two years and ten months after she stopped taking Pondimin. See Daubert brief at 32-33; Robbins Dep., 10/30/06, at 157:25-158:17, Ex. I. At that time, Plaintiff was admitted to a hospital in Tennessee where test results revealed an enlarged heart.<sup>12</sup>

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<sup>12</sup> The Plaintiff repeatedly describes this episode as “her first medically documented symptom of PPH” and her “first ‘documented’ symptoms.” Daubert Brief. at 32, 33, 37, fn. 56, 47, fn. 66.

- Over the next five years, Plaintiff frequently sought medical attention in Tennessee for similar symptoms — shortness of breath, passing out, fatigue, and swelling. See Report of Ivan Robbins, M.D.
- Wyeth mailed the Plaintiff the Initial Notice of the Class Action Settlement packet dated January 23, 2000, the Notice of Final Judicial Approval dated February 18, 2002, and the Notice of other deadlines dated February 3, 2003, to her address in Chattanooga, all before she filed her lawsuit.
- Plaintiff was diagnosed with pulmonary hypertension in Tennessee and had her qualifying heart catheterization in Tennessee.
- Plaintiff filed her lawsuit in a Tennessee state court.
- Plaintiff has been treated exclusively in Tennessee since her diagnosis, where she continues to reside.

Thus, Tennessee is the not merely the place of plaintiff's injury, it is also the place of ingestion, residence, diagnosis, treatment, location of the only direct communications between Wyeth and the Plaintiff, and the venue in which plaintiff chose to file her lawsuit. Given the extensive contacts with Tennessee *in addition to the place of injury*, Tennessee law governs the Plaintiff's claims.

Plaintiff's Complaint further indicates why Tennessee law applies. It alleges that:

- Pondimin "was expected to reach, and did reach, *consumers in the State of Tennessee, including Mrs. Montgomery*, without substantial change in the condition in which it was originally sold." See Complaint at ¶ 120. Thus, Plaintiff considers herself to be a *Tennessee* consumer relating to her use of Pondimin.
- The claimed "fraud and misrepresentation" on Mrs. Montgomery "*started as early as 1993, if not earlier*, and continued through repeated acts and non-disclosure every year since then..." Complaint at ¶ 150. There is no evidence that Plaintiff had a relevant contact with a state other than Tennessee prior to her use of Pondimin in 1997 or after she stopped using it.<sup>13</sup>

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<sup>13</sup> Plaintiff now attempts to retreat from this allegation in the Response, claiming that "Mrs. Montgomery makes no allegations that Wyeth engaged in any wrongful conduct in Tennessee." Pl's Opp. at 25. She has not, however, amended her Complaint.

- Plaintiff claims that “At all relevant times, [the Wyeth defendants] transacted business in the State of Tennessee and is therefore subject to the jurisdiction of this court pursuant to T.C.A. §20-2-214. *Wyeth had sufficient quantity of contact, nature and quality of contact and has a sufficient source and connection to the cause of action* in this case to give Tennessee long-arm jurisdiction over Wyeth.” See Complaint at ¶¶ 16-18.
- The clinic where Plaintiff obtained Pondimin “induced citizens from the State of Tennessee to cross state lines” in order to purchase Pondimin. Complaint at ¶ 21. The Response further admits that Plaintiff saw the clinic’s advertising while she was in Tennessee. Pl’s Opp. at 4.

The court’s decision in Trahan v. E.R. Squibb & Sons, Inc., 567 F.Supp. 505, 507 (M.D. Tenn. 1983) is instructive. There, the defendant manufacturer of DES moved for summary judgment claiming that North Carolina law applied to the Plaintiff’s claims relating to her *in utero* exposure to DES because the Plaintiff’s mother resided in North Carolina when she took DES and the Plaintiff was born in North Carolina. The plaintiff, however, argued that Tennessee law should apply because the Plaintiff later moved to Tennessee, where she became pregnant, where she was diagnosed with an incompetent cervix, and where she suffered her injuries. The Court held that Tennessee law applied, recognizing the substantial public policy reasons for applying Tennessee law where a latent injury manifests itself in Tennessee:

**Tennessee has the strongest public policy reasons for protecting its citizens against ingestion of dangerous prescription drugs and also for allocating the social cost of resulting injuries where the consumer is a resident of this state at the time of the manifestation of the injury. Damages, if any, to this plaintiff occurred in Tennessee. Hospital bills and doctor bills occurred in Tennessee. Economic loss results in Tennessee, and the risk of plaintiff or others becoming a public charge occurs in Tennessee.**

Id. at 510 (emphasis added). In contrast, the Court recognized that North Carolina would not bear any burdens of the alleged wrongdoing. Id. Similarly, in Teeters v. Curry, 518 S.W.2d 512, 516 (Tenn. 1974), the Tennessee Supreme Court held that:

Upon the basis of reason and justice, we hold that when an inherently unknowable injury, such as is here involved, has been suffered by one

blamelessly ignorant of the act or omission and injury complained of, *and the harmful effect thereof develops gradually over a period of time, the injury is “sustained” ... when the harmful effect first manifests itself and becomes physically ascertainable.*

As noted above, Trahan relied on Teeters to apply Tennessee law, holding that the place of injury for a DES claim was Tennessee, where the condition developed, and not the place of “the exposure to a drug with latent detrimental effects,” even where all of the DES had been used in North Carolina. 577 F. Supp. at 508. Plaintiff ignores both Teeters and Trahan, and Plaintiff’s reliance on cases not applying Tennessee law is unwarranted.<sup>14</sup> Plaintiff alleges that “the harmful effect first manifest[ed] itself” in Tennessee more than two years after she stopped using Pondimin. Under all these circumstances there is no doubt that Tennessee is the place of injury and has the most significant contacts.

Plaintiff also purports to rely on the misleading claim that “Pondimin was banned in Tennessee until just a few months prior to its withdrawal...” Pl’s Opp. at 23. In fact, Tennessee never banned the *use* of Pondimin in Tennessee, did not ban the prescription of Pondimin for the majority of the time Plaintiff used it, and, in fact, Pondimin was widely sold and available in approximately 700 Tennessee pharmacies during the time Plaintiff used it.<sup>15</sup> See Joslin Supp. Decl., ¶ 7, Ex. E. As Plaintiff admits, Pondimin “*was expected to reach, and did reach, consumers in the State of Tennessee, including Mrs. Montgomery...*” Complaint at ¶ 120.

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<sup>14</sup> Although Tennessee now applies the “most significant relationship” approach, which is more flexible than the *lex loci* approach used in Teeters and Trahan, they are consistent. Under the “most significant relationship” approach, the place of injury is the default rule (rather than dispositive) and is applied unless another state has more significant contacts. Indeed, the Hataway court noted that “generally the law of the state where the injury occurred will have the most significant relationship to the litigation.” Hataway at 59.

<sup>15</sup> It became legal to prescribe “phen-fen” in Tennessee on March 27, 1997, two months after the Plaintiff started taking Pondimin. See Senate Bill No. 1343, attached hereto as Ex. J, Tennessee Board of Medical Examiners Meeting Related to Phen-Fen (1995-1997), at p. 3, attached hereto as Ex. K. It remained legal to prescribe in Tennessee the rest of the time the Plaintiff used it.

Thus, Tennessee has a strong interest based on the use of Pondimin by one of its consumers. See Trahan, 577 F. Supp. at 508.

Plaintiff argues that the application of Tennessee's statute of repose would frustrate other interests Tennessee might have and might not be the best method of achieving the Legislature's intent to bring certainty to insurance coverage. This is a policy argument for the Tennessee Legislature, not this Court. See Kochins v. Linden-Alimak, Inc., 799 F.2d 1128, 1138 (6th Cir. 1986) ("we must remember that 'the drawing of lines that create distinctions is peculiarly a legislative task and an unavoidable one'"). Not surprisingly, Plaintiff's argument has been rejected by the Sixth Circuit in the two cases they rely upon, Kochins and Mathis v. Eli Lilly, 719 F. Supp. 134, 139 (6th Cir. 1982), both of which affirmed grants of summary judgment to the manufacturer under the statute of repose.

#### **D. Georgia Has Very Limited Contacts To This Case**

Plaintiff's claim that Georgia law applies in spite of the overwhelming contacts with Tennessee is without merit. No party is a Georgia resident and the clinic no longer exists. See Pl's Opp. at 5. Neither of the physicians who prescribed Pondimin to the Plaintiff are currently licensed to practice medicine in Georgia, and Dr. Shure is deceased. See Pl's Opp. at 6. Pondimin was not manufactured, packaged, or labeled in Georgia. See Joslin Decl. ¶14, Ex. C to Wyeth's Motion. Plaintiff does not claim that any of Wyeth's decisions relating to the manufacture, design, labeling, or marketing of Pondimin, or communications with the FDA about Pondimin, were made in Georgia. Further, Plaintiff does not claim to have suffered any symptoms of PPH in Georgia, does not claim to have actually had PPH in Georgia, was not

diagnosed in Georgia, and has not been treated in Georgia. Plaintiff herself also does not claim to have relied on any statements made by *Wyeth* in Georgia.<sup>16</sup>

Plaintiff claims that Georgia law should apply only because Plaintiff obtained her Pondimin pills there on seven occasions in 1997, she allegedly took a small number of Pondimin pills there, and that any warnings received by her prescribing physicians were received by them in Georgia. See Pl's Opp. at 5. These contentions do not support the application of Georgia law.

### **1. There is Little Relevant Evidence of Events That Occurred in Georgia**

Plaintiff's claim that her physicians received information from *Wyeth* in Georgia is not even supported by the record. Indeed the record is silent on whether the Plaintiff's prescribing physicians ever reviewed *Wyeth*'s warnings or relied on any other statements made by *Wyeth*. The physicians who actually prescribed Pondimin to the Plaintiff are Dr. Shure, who is deceased and was not deposed, and Dr. Hargett, who was not deposed, has already lost his license in Georgia, and has not been located. Further, the Plaintiff does not remember having any conversations with Drs. Shure or Hargett about Pondimin. Montgomery Dep., 7/26/06, at 189:4-191:2, Ex. F.<sup>17</sup> Accordingly, there is no evidence as to what, if any, warnings or other information about Pondimin Drs. Shure or Hargett actually saw in Georgia.

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16 The clinic's informed consent form did not contain a statement made by *Wyeth* and was not a contract entered into with *Wyeth*. Therefore, it cannot be the basis of a claim against *Wyeth*, and it is irrelevant to the Plaintiff's allegations against *Wyeth* whether the form had a governing law clause.

17 The testimony of Dr. Leon Lane, an employee of the clinic for part of the time the Plaintiff used Pondimin, does not support the application of Georgia law. Dr. Lane never treated or prescribed to the Plaintiff, was not employed at the clinic when Dr. Hargett prescribed to Plaintiff, does not pretend to know what information Drs. Shure or Hargett had about Pondimin or where they obtained it, and, contrary to the claim in the Opposition, his Declaration **does not even mention** the Pondimin labels that were operative at the time Plaintiff was prescribed it by Drs. Shure and Hargett.

Moreover, Plaintiff has no evidence that any Wyeth conduct *particular* to Georgia underlies Wyeth's alleged liability to the Plaintiff. Pondimin's labeling was drafted in Pennsylvania or Virginia and approved by the FDA at its offices in Maryland. Pondimin was not designed or labeled differently for Georgia, and the Complaint claims that Wyeth's misrepresentations were made to "the general public" and that Wyeth's supposed fraud occurred "throughout the United States and elsewhere." Accordingly, Georgia has no special interest in having its laws apply to Wyeth in this case, particularly when none of the parties are Georgia residents, the physicians at issue no longer practice there, the drugs were obtained by a Tennessee resident for her personal use in Tennessee, and where Tennessee law can address any interest Georgia might have.

The only relevant *evidence* relating to Georgia is that Plaintiff traveled from Tennessee in order to obtain Wyeth's product there and take it back to Tennessee. Plaintiff cites no Tennessee case applying the law of a state where a product was purchased when every other significant contact is with the forum state.

## **2. Georgia's Punitive Damage Laws Are Irrelevant**

Plaintiff's economic experts have never submitted reports based on Georgia law, so Plaintiff's sudden interest in applying Georgia's punitive damages law is dubious. Plaintiff nevertheless now claims that Georgia has a significant interest in this case because Georgia purportedly allows unlimited punitive damages in the context of product liability cases and Georgia itself recovers 75% of any punitive damages awarded. This argument puts the cart before the horse. As discussed above, there is no dispute that Pondimin and its PPH warnings were approved by the FDA, and Georgia does not allow punitive damages where the manufacturer complied with industry regulations. See Barger v. Garden Way, Inc., 231 Ga. App. 723, 728 (Ga. App. 1998); Stone Man, Inc. v. Green, 263 Ga. 470, 472 (Ga. 1993). Second,

Georgia's interest in this case is severely limited by the evidence and the overwhelming contacts in Tennessee. Because Georgia law has limited contacts relating to the underlying claims, issues relating to the award of punitive damages are irrelevant.

Another fatal flaw in Plaintiff's argument in the choice-of-law context is that Georgia has no pecuniary interest in having its punitive damages law apply because Georgia would not be receiving any punitive damages. Plaintiff cites no authority for the notion that a federal District Court in Tennessee, applying Tennessee choice-of-law rules to a case involving no Georgia parties or residents, no claimed violation of Georgia law, and no injury in Georgia, would be required to pay-out punitive damages to the state of Georgia that were awarded to a Tennessee resident. Such a procedure would impermissibly allow a state to dictate procedure to a federal court in another state, and indeed, Georgia's statute purports to create an affirmative duty to the clerk of the court to pay out the punitive damages to Georgia within 60 days. See OCGA § 51-12-5.1(e)(2). Accordingly, Georgia's punitive damage law does not demonstrate why Georgia law should apply to this case.

## **V. CONCLUSION**

For all the reasons set forth above, and in Wyeth's opening brief, the Tennessee statute of repose is applicable and requires the entry of Summary Judgment in Wyeth's favor.

Respectfully submitted,

WYETH and  
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Dated: February 7, 2008

**CERTIFICATE OF SERVICE**

I do hereby certify that on February 7, 2008, I electronically filed the foregoing document with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to the following:

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